

10515 U.S. PTO
1/07/97

A / FWC
Page 1 of 4
PATENT
APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK
OFFICE
REQUEST FOR FILE WRAPPER CONTINUING APPLICATION UNDER 37 CFR 1.62
(RULE 62)
For Design or Utility Applications

BOX FWC

The Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Prior Application: 08/583,491
Group Art Unit: 1818

Examiner: M. Allen

Atty Dkt: 241800/

new M#/Client Ref.

(Our Deposit Account No. 03-3975

(Our Order No. 20263/241800

, a C# / new M#

series code ↑ ↑ serial no.

Date: November 7, 1997

Sir:

This is a RULE 62 REQUEST for filing from
prior copending parent Application No. 08/583,491

divisional

continuation (**Exr. NOTE:** any election in parent as to species/restriction requirement:

is carried over with traverse is not carried over)

continuation-in-part without new Declaration (Rule 62(d)) without fee

continuation-in-part (with new Declaration attached hereto)

The parent was filed on January 5, 1996, entitled GDF-1,

by the following named inventor(s) who is/are the same as, less than all of (see Item 17),

more than (for CIP only), those named in that parent application:

(1) Inventor	Se-Jin	First	Middle Initial	Family Name
Residence	Baltimore	Maryland	USA	Country of Citizenship
Post Office Address (include Zip Code)	2509A Steele Road, Baltimore Maryland 21209			
(2) Inventor		First	Middle Initial	Family Name
Residence	City	State/Foreign Country	Country of Citizenship	
Post Office Address (include Zip Code)				
(3) Inventor		First	Middle Initial	Family Name
Residence	City	State/Foreign Country	Country of Citizenship	
Post Office Address (include Zip Code)				
(4) Inventor		First	Middle Initial	Family Name
Residence	City	State/Foreign Country	Country of Citizenship	
Post Office Address (include Zip Code)				
(5) Inventor		First	Middle Initial	Family Name
Residence	City	State/Foreign Country	Country of Citizenship	
Post Office Address (include Zip Code)				

NOTE: FOR ADDITIONAL INVENTORS, check box and attach sheet (CDC-110A) with same information with
same information for each inventor starting with inventor No. 6 and number new page 1A.

1. **Requirement of Rule 62:** Rule 62 filings are to be used only when the issue fee has not been paid (except as noted below) in the above-identified prior application nor that application abandoned or its proceedings terminated. This Rule 62 filing will be considered by the PTO as an express abandonment of that prior application except when this Rule 62 filing is pursuant to Rule 313(b)(5), i.e., when the issue has been paid in the prior application and a petition filed to abandon that application to permit an IDS to be considered in this Rule 62 application. (Note: 37 CFR 1.53 (Rule 53) may be used for continuations and divisions where the prior application is not to be abandoned.)

2. The issue fee has been paid in the parent, but this Rule 62 Request follows a Rule 313(b)(5) petition, and per 1138 OG 40 waiver is respectively requested of that part of Rule 62 which prohibits use of the rules to file an FWC after payment of the issue fee.

3. Priority is claimed under 35 U.S.C. 119/365 based on filing in _____ of: _____ (country)

<u>Application No.</u>	<u>Filing Date</u>	<u>Application No.</u>	<u>Filing Date</u>
(1) _____	_____	(4) _____	_____
(2) _____	_____	(5) _____	_____
(3) _____	_____	(6) _____	_____

a. (No.) Certified copy/copies attached.

b. Certified copy/copies previously filed on _____ in prior U.S. Application No. _____ / _____, filed on _____ series code ⇧ ⇧ serial no.

c. Certified copy/copies filed during International stage of PCT/ _____ / _____

d. Priority is also claimed from PCT/ _____ / _____ filed _____

4. The prior application is assigned of record to Carnegie Institution of Washington by Assignment recorded January 16, 1991 Reel 5582 Frame 0797.

5. Attached is an assignment Cover Sheet.
Please return the recorded Assignment to the undersigned.

6. The power of attorney in the prior application is to Paul N. Kokulis, Reg. No. 16,773

(Name, Reg. No.) ⇧

7. Recognize as associate attorney _____

(Name and Reg. No.; Address as in item 8 unless otherwise indicated) ⇧

8. **Address all future communications to Cushman Darby & Cushman, Intellectual Property Group of Pillsbury Madison & Sutro LLP, Ninth Floor, East Tower 1100 New York Avenue, N.W., Washington, D.C. 20005-3918**

9. Amend the specification by inserting before the first line (in place of any comparable insert previously requested in any prior application) the sentence: --This is a

continuation-in-part (CIP) continuation division

of application No. 08/583,491, filed on January 5, 1996, which was
series code ⇧ ⇧ serial no.

abandoned upon the filing hereof which is a continuation of Serial No. 08/316,456, filed October 3, 1994, now abandoned, which is a continuation of Serial No. 08/090,002, filed July 12, 1993, now abandoned, which is a continuation of Serial No. 07/614,452, filed November 16, 1990, now abandoned.

10. 1 (No.) Verified Statement(s) establishing "small entity" status under Rules 9 and 27

a. filed in above prior application (and hence applicable hereto)
b. attached.

11. **Requirement of Rule 62:** It is understood that secrecy under 35 U.S.C. 122 is hereby waived to the extent that if information or access is available to any one of the applications in the file wrapper of a 37 CFR 1.62 application, be it either this application or a prior application in the same file wrapper, the Patent and Trademark Office may provide similar information or access to all the other applications in the same file wrapper.

12. Petition to extend the life of the above prior application to at least the date hereof

NOTE: **(One box)** is being concurrently filed in that prior application (Use From CDC-111).
(must be) was previously filed in that prior application (Check length of prior extension).
(X'd) is not necessary for copendency (Double check before X'ing this box).

13. Please enter the amendment previously filed on _____
 but unentered in the above prior application.

14. Attached: _____ sheet(s) per set of drawing of Fig(s) :
 1 set informal; formal of size: A4 11"

15. **PRELIMINARY AMENDMENT to be entered before fee calculation** (Do not make amendments here except cancellation of whole claims or multiple dependencies for purpose of reducing the filing fee per MPEP §§ 506 and 607; do not cancel all claims.):

16. Attached is a Rule 103(a) Petition to suspend action

17. Petition is hereby made requesting deletion as inventor(s) of the following who is/are not inventor(s) of the invention being claimed in this Rule 62 application:

1. _____ 2. _____
 3. _____ 4. _____

18. This Rule 62 application is a continuation-in-part which discloses and claims additional matter and the amendments in attached Amendment are to be considered an integral part of the CIP ab initio.
 a. New Declaration is attached.
 b. This application is also filed under Rule 62(d) (without a Declaration) and hence filing fee is not enclosed.
FILING FEE

**THE FOLLOWING FILING FEE IS BASED ON THE CLAIMS
 EXISTING IN THE PRIOR APPLICATION AS AMENDED AT 13 AND 15 ABOVE**

				Large/Small Entity		Fee Code
19. Basic Filing Fee		Design Application		\$330/\$165		106/26
20.		Not Design Application		\$790/\$395	+395	101/201
21. Total Effective Claims	8	minus 20 =	0	x \$22/\$11	+0	103/203
(Base this \uparrow on claims as amended to effect CIP if this is a Rule 62(d) completion)						
22.. Independent Claims	1	minus 3 =	0	x \$82/\$41	+0	102/202
23. If <u>any</u> proper multiple dependent claim (ignore improper) is present, (Leave this line blank if this is a reissue application)				\$270/\$135	+0	104/204
24.				TOTAL FILING FEE =	\$395	
25. If "assignment" box 5 is X'd, add recording fee.			\$40	+	581	
26. If "petition" box 16 above is X'd, add petition fee.			\$130	+130	122	
27.				FEES ATTACHED =	\$525	
(carry forward to line 36)						

28. Preliminary Amendment attached (to be entered after assigning Appln. No.).
(Do NOT X box 28 or 29 for CIP Amendment. See box 18)

29. The following PRELIMINARY AMENDMENT is to be entered after assigning Appln. No.:

30. ATTACHED:
Request for Suspension of Action

**ADDITIONAL FEE CALCULATION FOR
PRELIMINARY AMENDMENT
PER BOXES 28/29**

Claims remaining after amendment	Highest number previously paid for	Present Extra	Additional Fee	Large/Small Entity	File Code
32. Total Effective Claims <u>15</u>	minus ** <u>20</u>	= * <u>0</u>	x \$22/\$11	= \$ <u>0</u>	(103/203)
33. Independent Claims <u>3</u>	minus *** <u>3</u>	= * <u>0</u>	x \$82/\$41	= + <u>0</u>	(102/202)
34. If amendment enters proper multiple dependent claim(s) into this application for the <u>first time</u> , add\$270/\$135(per application)				+ <u>0</u>	(104/204)
35.			ADDITIONAL FEE	\$ <u>0</u>	
36.		plus FEE from item 27 on page 3		+ <u>525</u>	
37.			TOTAL FEE ATTACHED	\$ <u>525</u>	

38. *If the entry in the first space is less than an entry in the middle space, the "Present Extra" result is "0"

39. **If the "Highest number previously paid for" (see item 21 above) is less than 20, write "20" in this space

40. If the "Highest number previously paid for" (see item 22 above) is less than 3, write "3" in this space

CHARGE STATEMENT: The Commissioner is hereby authorized to charge any fee specifically authorized hereafter, or any missing or insufficient fee(s) filed, or asserted to be filed, or which should have been filed herewith or concerning any paper filed hereafter, and which may be required under Rules 16-18 (missing or insufficient fee only) now or hereafter relative to this application and the resulting Official document under Rule 20, or credit any overpayment, to our Account/Order Nos. shown in the heading hereof for which purpose a duplicate copy of this sheet is attached. This CHARGE STATEMENT does not authorize charge of the issue fee until/unless an issue fee transmittal form is filed.

**Cushman Darby & Cushman
Intellectual Property Group of
Pillsbury/Madison & Sutro LLP**

1100 New York Avenue, N.W. By: Atty Paul N. Kokulis Reg. No. 16,773
Ninth Floor East Tower
Washington, D.C. 20005-3918 Sig: Paul C. Kunkel Reg. No. 34,610
Tel: (202) 861-3000 Fax: (202) 822-0944
PNK/GRT/hc Tel: (202) 861-3503

NOTE: No. 1: File this Request in duplicate with 2 postcard receipts (CDC-103) & attachments
NOTE: No. 2: Is extension in parent necessary for copendency? **DOUBLE CHECK** Item 12 above.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

LEE

FWC of Appln. No. 08/583,491

Group Art Unit: 1818

Filed: November 7, 1997

Examiner: M. Allen

FOR: GDF-1

* * *

November 7, 1997

PRELIMINARY AMENDMENT

Honorable Commissioner of
Patents and Trademarks
Washington, D.C. 20231

Sir:

Entry and consideration of the following amendment and
remarks prior to examination are respectfully requested.

IN THE CLAIMS:

Please amend the claims as follows.

22. (Twice Amended) An [The] isolated DNA segment
[sequence] encoding mammalian GDF-1 protein having an [the]
amino acid sequence defined in an open reading frame of Figure
2 or Figure 11A or Figure 11B.

Please cancel claim 23 without prejudice and add the
following new claims.

--24. An isolated DNA segment encoding mammalian GDF-1 protein comprising a nucleotide sequence as defined in an open reading frame of Figure 2 or Figure 11A or Figure 11B.

25. The isolated DNA segment according to claim 24 further comprising a nucleotide sequence outside the open reading frame as defined in Figure 2 or Figure 11A or Figure 11B.

26. A recombinant DNA molecule comprising the isolated DNA segment according to claim 25 and a vector.

27. A host cell stably transformed with the recombinant DNA molecule according to claim 26.

28. The host cell according to claim 27 wherein said cell is a prokaryotic cell.

29. The host cell according to claim 27 wherein said cell is a eukaryotic cell.

30. A method of producing a recombinant GDF-1 protein comprising culturing the host cell according to claim 27 under conditions such that the GDF-1 protein is produced, and isolating the GDF-1 protein.

31. An isolated DNA sequence complementary to the DNA sequence encoding mammalian GDF-1 protein having the nucleotide sequence defined in Figure 2 or Figure 11A or Figure 11B at hybridization conditions of 68°C and 1M sodium chloride and which remains bound when subjected to washing at 68°C with 15 mM sodium chloride/1.5 mM sodium citrate.--

REMARKS

The Examiner's attention is directed to the accompanying petition submitted under 37 C.F.R. 1.103(a); the petition request suspension of action in the present application. A decision on this petition is requested prior to examination and issuance of a first Office Action. If the declaration has not reached the Examiner when this application is taken up for examination, she is invited to contact the undersigned.

Claims 3, 11-15, 22 and 24-31 are pending. Claim 23 was canceled without prejudice as the claimed subject matter will be prosecuted in a separate application. New claims 24-31 are directed to the native DNA sequence of the mammalian GDF-1 gene and its uses as a hybridization probe.

The amendments to the claims find support throughout the original disclosure and, thus, do not introduce new matter. See, in particular, pages 9-10 of the specification.

Claims 3, 11-15 and 22 were rejected under 35 U.S.C. 112, first paragraph, as allegedly indefinite. Applicant traverses. Contrary to the statement on page 2 of the Office Action (Paper No. 34), applicant has not admitted that "the description of recombinant production of GDF-1 in the specification and the description of Figure 9 is insufficient". In fact, pages 11-12 of the specification describes vectors and host cells used in production of recombinant GDF-1, and Figure 9 shows cell-free production of recombinant GDF-1. Applicant submits that such provides support in the specification for how the invention is made and used. The withdrawal in the pending Office Action of the portion of the enablement rejection directed to the specification teaching how the claimed invention is made is indicative that the specification provides such an enabling disclosure.

With respect to the objection that the specification does not teach how the claimed invention is used, applicant submits that the arguments made in the previous response and maintained here are sufficient disclosure to be enabling. In particular, applicant has not attempted "to add statements of usefulness to the disclosure of the application as filed", page 5 of the Office Action (Paper No. 34). Instead, the use of GDF-1 as a lineage marker as shown in the specification establishes that the skilled artisan could use the claimed

invention, either by hybridization or by detection of GDF-1 protein.

Although applicant maintains that this is sufficient to overcome the Examiner's objection to the specification, a declaration is being prepared to further prosecution in the present application. As discussed in the petition, suspension is requested to allow applicant time to prepare a declaration containing evidence responsive to the pending enablement rejection. Such declaration evidence should be further considered as a response to the pending enablement rejection.

Claims 3, 11-15 and 22 were rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite. Applicant traverses. It is clear that the GDF-1 protein is being claimed and that the second, upstream open reading frame shown in Figures 2, 11A and 11B is UOG-1 (see Examples 7 and 8, and page 15, lines 16-18 of the disclosure). Thus, the amino acid sequence of the downstream open reading frame is the claimed GDF-1 protein.

Finally, it is noted that the Hoben et al. reference supports the use of GDF-1 as a lineage marker because of its expression "primarily in the nervous system". Further, the cited abstract does not support the Examiner's allegation that "biological activity, and assays therefore, for GDF-1 had not been determined at the time of invention" (page 5 of the Office Action, Paper No. 34). Instead the abstract describes

LEE - FWC of Appln. No. 08/583,491

further characterization of GDF-1 and studies showing that recombinant GDF-1 "stimulates the expression of the immediate early genes in neural cell lines". Thus, one would not conclude from the abstract that GDF-1 does not have a biological activity or that such activities as disclosed in the present application are incredible.

A favorable action on the merits is earnestly requested. If any further information is required, the Examiner is invited to contact the undersigned.

Respectfully submitted,

Cushman Darby & Cushman
Intellectual Property Group of
PILLSBURY MADISON & SUTRO, L.L.P.

Paul C. Kokulis
By *for* Paul N. Kokulis
Reg. No. 34,610
Reg. No. 16,773
Telephone: (202) 861-3503
Facsimile: (202) 822-0944

PNK/GRT
1100 New York Avenue, N.W.
Ninth Floor, East Tower
Washington, D.C. 20005-3918
Phone: (202) 861-3503